activities" including a "common communication network by which the Defendant Drug Manufacturer and the specific PBM share information on a regular basis." ¶ 653. Through setting the AWP, "[e]ach Defendant Drug Manufacturer has directly controlled the price for its AWPIDs, which determines the amount of each of the PBMs' compensation." ¶ 667(a). Further, each Defendant "directly controlled the creation and distribution of marketing, sales, and other materials used to inform each of the PBMs of the profit potential of its AWPIDs," ¶ 667(d), and

> controlled and participated in the affairs of the Manufacturer-PBM Enterprises with which they are associated by providing or receiving rebates (as detailed above) or other inducements to place a certain Defendant Drug Manufacturer's AWPIDs on a PBM formulary or advocate the use of a certain AWPID. These inducements include drug manufacturers' payment to PBMs of: (i) access rebates for placement of products on the PBMs' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants. Although PBMs typically agree to share rebates in some form with clients, they link the rebates to formulary savings in such a manner that the PBM often is able to secretly retain all of the rebates. Furthermore, PBMs refuse to disclose specific rebate amounts to clients in any fashion other than in the aggregate compared to performance standards, thereby preventing the client from learning the true amount of rebates that the PBM has received in connection with the health plan client. [¶ 667(f).]

Finally, and as noted, each PBM, wanting to receive as many secret rebates and other undisclosed inducements, "took instructions and commands from the manufacturers regarding the use of AWP . . . ." ¶ 657.

There can be no doubt that the above allegations of control over both the Manufacturer-Publisher Enterprises and the Manufacturer-PBM Enterprises are sufficient to demonstrate that each Defendant plays "***some*** part in directing the enterprise's affairs." *Reves*, 507 U.S. at 179 (emphasis added); *Aetna*, 43 F.3d at 1559.

Citing only one case, *Arrandt v. Steiner Corp.*, 2001 U.S. Dist. Lexis 11410 (N.D. Ill. Aug. 6, 2001), Defendants claim that "the AMCC alleges nothing more than actions by the

manufacturers involving their own affairs" and that, consequently, Plaintiffs have failed to set forth facts demonstrating that Defendants conducted or participated in the affairs of the enterprises. Defs. Mem. at 19-20. Unlike here, in *Arrandt*, the defendant merely sent an invoice containing an allegedly fraudulent charge, and this allegation alone was insufficient to properly plead some involvement in the direction or control of the plaintiff's business. Without more, the court held that the complaint "alleges only that [defendant] is providing a service for which it seeks and collects payment and thus is directing only its own, and not the plaintiff enterprise's, affairs." 2001 U.S. Dist. Lexis 11410, at *12.

In contrast, Defendants here controlled the AWPs published by the Publishers. *See* ¶¶ 136, 627, 634-36. And this does not mean that each Defendant was merely conducting its own affairs by doing so. The business of a drug company is to development, manufacture and sell pharmaceuticals; "conducting the usual affairs" of a drug company does not (or at least should not) include reporting fraudulent reimbursement AWPs to effectuate profiteering. Moreover, Defendants have been under no obligation to use these publishing companies, nor have they been obligated to report fraudulent AWPs to them, but they did so in order to further their AWP fraud scheme ***through*** the RICO enterprise. Without the enterprise and the scheme, Defendants would not be able to push the spread. ¶ 624; *see also* ¶ 137 ("A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers. The Defendant Drug Manufacturers knew they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP."). And it is difficult to envision how Defendants could exert greater control over the enterprise given the Publisher's admissions that they publish "pricing information . . . supplied and verified by the products' manufacturers" without "independent review of those prices for accuracy." ¶ 136.

Defendants exercise a similarly large degree of control over their respective Manufacturer-PBM Enterprises given that, by setting the AWP, each Defendant determines the

pricing in turn received by the PBMs' from their own clients. ¶¶ 171-72, 657, 667(a). Defendants also affect the composition of PBM drug formularies by reporting inflated AWPs for certain drugs: the "PBMs are motivated to, and do place on their formulary those drugs with inflated AWPs . . . ." ¶ 171. This, too, is a stark contrast to the skinny allegations at issue in *Arrandt*.

Plaintiffs have sufficiently alleged that Defendants controlled and participated in the respective Manufacturer-Publisher and Manufacturer-PBM Enterprises. These are ample allegations of control and participation, and the First Circuit requires nothing more.

D. Plaintiffs Have Standing to Sue Defendants for RICO Violations

1. Plaintiffs have adequately alleged direct injury to business or property

To establish standing to sue under RICO, Plaintiffs must allege some direct relationship between the injury sustained and the alleged racketeering activity (mail and wire fraud). *See Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268-70 (1992); *Camelio v. American Fed'n*, 137 F.3d 666, 669 (1st Cir. 1998).

Under this analysis, and notwithstanding Defendants' arguments to the contrary (*see* Defs. Mem. at 20-23), the allegations of the AMCC are more than sufficient because Plaintiffs allege a direct connection between Defendants' AWP Scheme, their alleged acts of mail and wire fraud, and the multi-million dollar overpayments made by Plaintiffs and Class members. ¶¶ 644-46, 677-79. The AMCC alleges that Plaintiffs and Class members are the targets of Defendants' AWP Scheme. ¶ 3. The sole purpose of Defendants' pattern of racketeering activity (the alleged acts of mail and wire fraud) was to "deliberately overstat[e] the AWPs for their AWPIDs, thereby creating a 'spread' based on the inflated figure in order to induce others to advocate and favor that Defendant Drug Manufacturer's AWPIDs" and "to ensure that Plaintiffs and members of the Class would be over-billed for the drugs." ¶¶ 638-39; *see also* ¶¶ 671-72. Further, the AMCC alleges that, even though Plaintiffs and the class members are making reimbursements to

third parties for the drugs purchased, those reimbursements are made based upon the AWPs set ***directly*** by Defendants:

> Plaintiffs and other Third-Party Payors also typically make reimbursement to health care providers for pharmaceuticals based upon the AWP. Accordingly, Third-Party Payors are ***directly*** damaged by fraudulent AWP pricing schemes for drugs covered by employee health and benefit plans or by private insurance because reimbursement is also typically based on the AWP, as in the case of Medicare and Medicaid reimbursement. [¶ 541 (emphasis added).]

These allegations are more than sufficient to allege standing to sue under Section 1964(c) of RICO and satisfy the causation tests established by the Supreme Court in *Holmes*, 503 U.S. at 268-70. *See, e.g., Commercial Cleaning Servs., L.L.C. v. Colin Serv. Sys., Inc.*, 271 F.3d 374, 384 (2d Cir. 2001) (collecting cases); *Mid Atl. Telecom v. Long Distance Servs.*, 18 F.3d 260, 263 (4th Cir. 1994). *Cf. Hamm v. Rhone-Poulenc Rorer Pharms.*, 187 F.3d 941, 952-53 (8th Cir. 1999).[23]

Given the facts and circumstances of this case, the RICO causation analysis offered by Judge Wolf of this District in *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 83-85 (D. Mass. 1998), is particularly applicable. In that case, a building owner and shopping center owner filed a class action against defendants, a distributor and fiberglass component supplier for the roof insulation that had been installed on the owners' roofs. The owners asserted civil RICO claims, contending that the roof insulation caused the owners' roofing systems to corrode, thereby causing injury to their "business or property." In response to defendants' motions to dismiss, the owners contended that they satisfied RICO's standing requirements because they alleged that defendants' misrepresentations and omissions constituted the proximate and factual cause of their injuries. *Id.* at 81. Rejecting defendants' claim that plaintiffs' RICO claims should be dismissed because the owners did not allege "reliance" upon the alleged predicate acts of mail and wire fraud (the alleged misrepresentations concerning the fiberglass insulation

[23] It should be noted that *Holmes* does not require that civil RICO plaintiffs must allege that they were the "targets" of defendants' scheme to defraud; however, that is one way to satisfy the standing requirements of Section 1964(c). *See BCCI Holdings (Lux.), S.A. v. Khalil*, 214 F.3d 168, 174 (D.C. Cir.), *cert. denied*, 531 U.S. 958 (2000).

having been made to the plaintiff owners' predecessors), *id.* at 81-83, Judge Wolf found that each element of RICO causation had been properly alleged:

> Allowing [the plaintiff owners] to advance their RICO claims against these defendants will not create administratively inconvenient or unmanageable litigation. Nor will these plaintiffs' claims lead to duplicative recoveries. Finally, recognizing that these plaintiffs have standing will further RICO's statutory goal of encouraging directly injured victims to act as private attorneys general to vindicate the law. Here, the plaintiffs are owners of buildings allegedly damaged by latent defects of PFRI. Because of the latent nature of the damage allegedly caused by PFRI, the former owner of [plaintiff] Sebago's building cannot reasonably be described as having been directly injured. Rather, the plaintiffs as present owners of buildings with alleged structural damage caused by PFRI's latent defects can be said to have been "truly injured in some meaningful sense." As such, allowing plaintiffs to press their claims here will further RICO's statutory goal of encouraging directly injured victims to act as private attorneys general to vindicate the law. [*Id.* at 83 (quoting *Holmes*, 503 U.S. at 279 (O'Connor, J., concurring)).]

Judge Wolf also found that the plaintiffs had alleged that they were among the "intended victims" of the defendants' scheme to defraud. *Id.* at 83-84. Thus, assuming (as we must) that defendants "have committed the acts alleged," *id.* at 85, the court explained:

> [I]t is for a jury apply the law of proximate causation and decide whether the plaintiffs were in the zone of foreseeable plaintiffs and whether the defendants' actions were a substantial factor in causing the plaintiffs' harm. *Peckham v. Continental Cas. Ins. Co.*, 895 F.2d 830, 837 (1st Cir. 1990) (holding that questions of causation "are normally grist for the jury's mill."); *Swift v. United States*, 866 F.2d 507, 510 (1st Cir.1989) ("Application of the legal cause standard to the circumstances of a particular case is a function ordinarily performed by, and peculiarly within the competence of, the factfinder."); W. Prosser & W. Keeton, Prosser and Keeton on Torts 321 (5th ed. 1984) ("'proximate cause is ordinarily a question of fact for the jury, to be solved by the exercise of good common sense in the consideration of the evidence of each particular case.'") (citation and footnotes omitted). Thus, the court cannot properly rule as a matter of law that plaintiffs were outside the zone of foreseeable plaintiffs or that the defendants' actions were not a substantial factor. To the contrary, accepting the plaintiffs' allegations as true and drawing all reasonable inferences from them, ***it appears that both plaintiffs were among the intended victims of the alleged fraud.*** For purposes of these motions to dismiss, therefore, plaintiffs adequately plead causation and state a substantive RICO claim.

Id. (emphasis added). The same principles apply in this case, and the Court should reject Defendants' contention that Plaintiffs do not properly allege RICO standing.

2. There are no intervening acts that break *Holmes* causation

Defendants claim that a number of purported intervening acts "break the causal chain of plaintiffs' RICO claims," Defs. Mem. at 21, citing (i) misrepresentations made to third-party publishers and not to plaintiffs, (ii) the prescribing doctor's submission of the claims for reimbursement to Medicare carriers, (iii) Congress's choice to base reimbursements on AWP, and (iv) in the case of PBMs, the PBMs, not the defendants, contract with the health plans. Defs. Mem. at 21-23. None of these events serve to vitiate proximate cause under the test articulated in *Holmes*.

The Supreme Court in *Holmes* instructed courts to ask three questions in determining whether allegations sufficiently plead direct causation: (i) are the damages too difficult to prove; (ii) will there be any difficulty in apportioning damages; and (iii) are other parties in a superior position "to bring suit for the law's vindication"? 503 U.S. at 273. Each question is answered in favor of Plaintiffs here.

First, there will be no difficulty in proving damages because, as alleged, Defendants set the AWP and therefore the reimbursement base directly. This is best illustrated by referencing an example cited in the AMCC. Paragraph 466 documents a number of instances in which the DOJ determined that Defendant Pharmacia reported AWPs that were substantially higher than the actual prices listed by wholesalers. For one of these drugs, Bleomycin Sulfate, the Pharmacia Group reported to *Red Book* an AWP of $309.98, when the DOJ determined that the actual AWP was $158.67 – a spread of $151.31 or 96 percent. A member of the AWP Payor Class who made a 20 percent co-payment for this drug under, for example, Medicare, would have paid $62 based on the phony AWP. This class member was damaged in the amount of $30.26, or 20 percent of the $151.31 spread.

A member of the PBM Third-Party Payor Sub-Class would also be damaged in a direct manner. If this Class member had contracted with a PBM to pay AWP less 13 percent for drugs (a common contract formula, *see* ¶ 171), the damage would be $126.64 as follows:

	Payment Based on Phony AWP	**Payment Based on Accurate AWP**
AWP	$309.98	$158.67
Less 13%	40.30	20.63
Payment	$269.68	$138.04
Difference (damage)	**$126.64**	

The simple payment relationships and direct injury set forth in both of the examples above, indicate that damages are calculable.

In both examples and in all instances either a Part B drug or a non Part B drug, the AWP is set ***directly*** by Defendants and used, ***exactly as reported by each Defendant***, in the calculation of the payments made by each Class member. The so-called "intervening actors" who were provided incentives to act as Defendants instructed, merely advanced – and did not break – the chain of causation that began with Defendants.

Second, there is no issue here of apportioning damages among Plaintiffs and Class members who have been harmed by the same injury. Plaintiffs allege injury to each of them and to each Class member: the amount of money that the person or entity paid out of pocket as a direct consequence of the AWP Scheme. ¶¶ 644-46, 677-79. Thus, the direct injuries alleged here are unlike the indirect injuries at issue in *Holmes*, where the plaintiff's injuries were derived from injuries inflicted first on broker-dealers and then, by virtue of the broker-dealer liquidations, on plaintiff Securities Investor Protection Corporation who advanced nearly $13 million to cover investor claims. 503 U.S. at 273.

Turning to the third *Holmes* inquiry, no other party has been more directly injured for purposes of vindicating the damages alleged (unlike the broker-dealers in *Holmes*, who the court found to be superior plaintiffs). In fact, ***no one else has suffered the co-pay injury, and no one else has suffered the payor's injury; these injuries are direct.*** Thus, it is not a matter of looking

for "superior" or more directly injured plaintiffs. The plain matter is that, apart from the Plaintiff end-payors, Defendants have not identified any more directly injured persons because non exist.

Indeed, at least one Defendant – the GSK Group – concedes direct causation. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the direct implications of increasing the AWP to create a better spread:

¶ 395 (quoting (GSK-MDL-Z01-05675) (Highly Confidential) (emphasis added)).

In sum, because Defendants directly set the reimbursement base (the AWP), every Plaintiff and Class member is directly harmed. It is immaterial that Defendants make the AWP misrepresentation to third-party publishers and not to Plaintiffs, that the prescribing doctor and not the patient submits claims for reimbursement,[24] that Congress chose to base reimbursements

[24] Defendants claim that the prescribing doctor has the discretion to submit reimbursement invoices for a charge lower than AWP less than 95%, Defs. Mem. at 22, but this ignores Plaintiffs' controlling allegations that all providers base reimbursement on AWP. Furthermore, and although it is premature to resolve this factual issue, Defendants will be unable to show that providers in practice actually request reimbursement at a ***lower*** rate than AWP less 5 percent.

on AWP instead of some other formula,[25] and that PBMs, not the Defendants, contract with the health plans. None of these events detract from the direct injury inflicted upon Plaintiffs and the Class by Defendants' direct AWP reporting. The Court should reject Defendants' standing/causation challenge.

VI. COUNT IX PROPERLY PLEADS CIVIL CONSPIRACY

A. The AMCC States a Claim for a Concerted Action Civil Conspiracy[26]

To state a claim for the independent tort of conspiracy, Plaintiffs must allege that two or more co-conspirators combined to accomplish an unlawful purpose or to accomplish a purpose not unlawful by unlawful means. *Queeno v. Cote*, 1999 Mass. Super. Lexis 506, at *8 (Mass. Sup. Ct. 1999); *Baron v. Smyly*, 1995 Mass. Super. Lexis 454 (Mass. Sup. Ct. 1995).

Plaintiffs allege that two or more co-conspirators combined to accomplish an unlawful purpose. *Baron*, 1995 Mass. Super. Lexis 454, at *9. More specifically, the AMCC alleges a combination between each Defendant and a PBM for the wrongful purpose of perpetuating a reimbursement system based on fraudulently-overstated AWPs in order to defraud all persons and entities that pay for drugs based on AWP. ¶¶ 168-76, 729. Importantly, a conspiracy claim should be sustained where "the alleged unlawful goal was the defrauding of the plaintiffs." *Queeno*, 1999 Mass. Super. Lexis 506, at *8.

Alternatively, Plaintiffs allege that two or more co-conspirators combined to accomplish a purpose not unlawful by unlawful means. *Baron*, 1995 Mass. Super. Lexis 454, at *9. More specifically, the AMCC alleges that, even if Defendants had a right to increase their prices (a purpose not unlawful), the combination of the Defendants and PBMs was for the purpose of

[25] It bears repeating that Plaintiffs' claims are ***not*** predicated on Congress's decision to use AWP as the reimbursement benchmark for Medicare. Rather, the fraud challenged here is Defendants' choice to game the system by reporting false and fraudulent AWPs; Defendants' conduct, not Congress's, is where the focus belongs. In any event, Congress's decision has no relevance to the Class claims involving payments outside of Medicare. To reiterate, the use of published AWPs to establish reimbursement rates for drugs is an ***industry-wide practice*** used outside of the Medicare context. *See, e.g.*, ¶ 134.

[26] Defendants also assert that Plaintiffs fail to allege a coercive conspiracy. Defs. Mem. at 27-28. Plaintiffs did not plead a coercive conspiracy and thus do not respond to Defendants' arguments on that point in this memorandum.

accomplishing reimbursement inflation through unlawful means, namely hiding the artificial inflation behind the phrase "average wholesale price." ¶¶ 168-76, 729.

Under either scenario, Plaintiffs allege sufficient facts to demonstrate the existence of "first, a common design or an agreement, although not necessarily express, between two or more persons to do a wrongful act and, second, proof of some tortious act in furtherance of the agreement." *Defonseca v. Sandler*, 2002 Mass. Super. Lexis 250, at *9-10 (Mass. Sup. Ct. 2002).

Here, the common design or agreement was the agreement to use AWP as the basis for prescription drug payments when both the Defendants and PBMs knew it was an inflated number. The tortious act in furtherance of these agreements was to purposefully inflate AWPs to prices far in excess of the average prices available to providers and to do so without telling the Class – the persons and entities that were paying for prescription drugs based on AWP. Specifically, the AMCC describes how, for brand name drugs administered outside the Medicare Part B context, Defendants specifically marketed the inflated AWP, the price on which Plaintiffs' payments are based, to PBMs and other intermediaries in order to induce them to place those drugs on their formularies. The AMCC also alleges that this scheme encourages intermediaries to place drugs on formularies based on their desire to increase their profitability by creating a spread. ¶¶ 168-76.

Defendants rely on *Massachusetts Laborers' Health & Welfare Fund v. Philip Morris, Inc.*, 62 F. Supp. 2d 236 (D. Mass. 1999), where this Court dismissed a civil conspiracy claim where the operative complaint "quite clearly allege[d] that the defendants acted jointly pursuant to a common scheme" but where the complaint failed to allege that "acting in concert, [defendants] committed a tort, such as misrepresentation." *Id.* at 245. But *Massachusetts Laborers* helps Plaintiffs, not Defendants. Plaintiffs unequivocally allege a misrepresentation proffered by Defendants and perpetuated by, *inter alia*, the PBMs. The AMCC alleges that Defendants set artificially inflated prices for their drugs, which prices were misrepresented to be

the "average wholesale prices" of those drugs. *See, e.g.*, ¶ 3 ("AWPs . . . are deliberately false and fictitious and created solely to cause Plaintiffs and the Class members to overpay for drugs."); ¶ 6 ("the Defendant Drug Manufacturers often promote their drugs not based on lower prices, but by use of reimbursement rates based on a fictitious and inflated AWP that allows . . . PBMs . . . to make inflated profits . . . ."); ¶ 138 ("the AWPs for the drugs at issue here bore little relationship to the drugs' pricing in the marketplace. They were simply fabricated and overstated in furtherance of Defendants' scheme to generate the profit spread to . . . PBMs . . . ."). The AMCC further alleges that the PBMs are motivated to place drugs on their formularies with inflated AWPs, because the PBMs will then pocket a greater spread or differential between the charges paid to pharmacies versus the amount collected from health plans. ¶ 171. Pursuant to *Massachusetts Laborers*, Plaintiffs' allegations that Defendants acted in concert with the PBMs to misrepresent and artificially inflate the AWPs, and to use those artificially inflated prices as the basis for reimbursement by Plaintiffs and the Class members, is sufficient to state a claim for a concerted action conspiracy under Massachusetts law.

Defendants also complain that the conspiracy count should be dismissed because it duplicates Plaintiffs' RICO and consumer fraud claims. Defs. Mem. at 28. However, it is clear that, under Massachusetts law, "a fraud, if proven, may be the basis for several forms of relief by an aggrieved person." *Queeno*, 1999 Mass. Super. Lexis 506, at *9. Here, Defendants' fraudulent manipulation of AWPs has manifested itself in multiple wrongs to multiple victims including Plaintiffs and Class members here. Defendants must now be required to answer for each of the manifestations resulting from the tortious scheme they and others chose to perpetuate.

B. The Civil Conspiracy Claim Complies With Rule 9(b)

The AMCC includes detailed allegations of each Defendant's inflated AWPs, and a detailed explanation of how the AWP fraud impacts health plans and their participants outside the Medicare Part B context through the PBMs. Nonetheless, Defendants claim that Plaintiffs

only allege conclusory allegations about a conspiracy between Defendants and the PBMs. Defs. Mem. at 24-26. But a careful reading of the AMCC reveals that Plaintiffs detail each facet of the conspiracy between the manufacturers and PBMs and the inner workings of the PBM system, including:

- As fiscal intermediaries between Defendants and health plans and their participants, PBMs use inflated AWPs set by Defendants as the basis for reimbursement (i) made by health plans to PBMs for their participants' drug purchases; and (ii) from the PBMs to pharmacies for the purchases made by health plans' members. ¶¶ 70-71.

- PBM contracts with health plans require that health plans pay for Defendants' brand name drugs at the published AWP less a certain percentage "discount" ("Health Plan Payments"). ¶ 168.

- PBM contracts with pharmacies typically require the PBM to reimburse the pharmacy an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee ("Pharmacy Reimbursement"). PBMs refuse to disclose the terms or amount of the Pharmacy Reimbursement to health plans. ¶¶ 171, 174.

- PBMs then frequently pocket the undisclosed spread or differential between the Pharmacy Reimbursement and the Health Plan Payments based on AWP and the true AWP. ¶¶ 171, 175.

- PBMs conduct business with repackagers, who sell a repackaged drug with a higher price. PBMs negotiate a "discount" with the repackager at a higher and phony AWP, and keep the higher spread they receive. ¶ 171.

- Defendants thus encourage PBMs to place their drugs on the PBMs' formularies by inflating AWPs, because the drugs with the more inflated AWPs result in greater profits to the PBMs. ¶¶ 171, 176; *see also* ¶ 6 ("the Defendant Drug Manufacturers often promote their drugs not based on lower prices, but by use of reimbursement rates based on a fictitious and inflated AWP that allows . . . PBMs . . . to make inflated profits.").

These allegations are sufficient to put Defendants on notice of "[t]he general outline of the general scheme to defraud" and therefore satisfy Rule 9(b). *Kuney*, 746 F. Supp. at 237. Plaintiffs "must allege the circumstances of the fraud," as they have, but are "not required to plead all of the evidence or facts supporting it." *Parke-Davis*, 147 F. Supp. 2d at 46-47. Furthermore, Plaintiffs are not required to identify the content and speaker of every statement made in furtherance of Defendants' scheme as long as Plaintiffs have sufficiently described the mechanisms of that scheme. *See Rolo v. City Inv. Co. Liquidating Trust*, 155 F.3d 644, 658 (3d

Cir. 1998) (Plaintiffs "need not, however, plead the 'date, place or time' of the fraud, so long as they use an 'alternative means' of injecting precision and some measure of substantiation into their allegations of fraud.") (citation omitted). Plaintiffs have clearly satisfied that standard by detailing the mechanisms of how Defendants have worked to conspire with and perpetuate the AWP Scheme through the PBMs.

VII. COUNT IV PROPERLY PLEADS VIOLATIONS OF STATE CONSUMER PROTECTION STATUTES

Defendants' second attempt to obtain dismissal of Plaintiffs' state consumer protection claims is as unfounded as the first attempt and, for the reasons presented below, should again be rejected.

A. Plaintiffs Have Properly Pled Causation

At this stage in the litigation, Plaintiffs need only aver, not prove, a causal connection between Defendants' deceptive conduct and the harm that Plaintiffs have suffered. According to Defendants, Plaintiffs have failed to sufficiently allege that Defendants "directly and proximately" caused their injuries under the consumer protection laws of Florida, Illinois, Louisiana, New Jersey, New York, Pennsylvania, Texas, and Washington. Defs. Mem. at 29-30. Defendants once again misconstrue the AMCC.

The AMCC is replete with allegations that Plaintiffs' injuries were caused ***as a direct result of*** Defendants' deceptive practices, including the following examples:

> The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs . . . directly caused Plaintiffs and the members of the Class to substantially overpay for those drugs.
>
> * * *
>
> The wrongful conduct alleged in this Complaint . . . has caused great harm to Plaintiffs and the Class, who were foreseeable and direct victims . . . .
>
> * * *

> As a direct and legal result of Defendants' misleading, deceptive, unfair, false and fraudulent trade practices, Plaintiffs and the Class have sustained injuries.

¶¶ 140, 689, 691. Furthermore, Plaintiffs repeatedly allege that the deceptive acts of each individual Defendant "***resulted*** in excessive payments by Plaintiffs and the Class." *See* ¶¶ 216, 230, 249, 270, 285, 299, 313, 326, 341, 363, 375, 416, 421, 434, 443, 448, 475, 491, 505, 520, 539 (emphasis added.) Plaintiffs further aver causation in connection with their antitrust claims involving the Together Rx Card (¶¶ 545, 587, 724) and for each of their claims for conspiracy. ¶¶ 733, 741.

Plaintiffs also sufficiently allege that Defendants ***proximately*** caused their injuries. "Proximate cause" means any cause that, in natural or probable sequence, produced the injury complained of. *Capiccioni v. Brennan Naperville, Inc.*, 791 N.E.2d 553, 561 (Ill. App. Ct. 2003) (finding proximate cause pled in consumer fraud claim). The AMCC repeatedly alleges proximate cause. *See* ¶¶ 644 ("[t]he Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Classes to be injured."); 689 ("The wrongful conduct alleged in this Complaint…has caused great harm to Plaintiffs and the Class, who were foreseeable and direct victims."); 724 ("[t]he violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and the members of Nationwide End Payor Together Card Class to be injured"); 733 ("[a]s a direct, proximate result of this [PBM] conspiracy, Plaintiffs and Class Members have been injured"); and 741 ("[a]s a direct, proximate result of this [Together Card] conspiracy, Plaintiffs and Nationwide End Payor Together Card Class Members have been injured").

Defendants contend that Plaintiffs cannot show that Defendants were the direct and proximate cause of their injuries because the AMCC alleges an "attenuated causal chain" involving several intervening actors that contributed to the deception of Plaintiffs. Defs. Mem. at 29-30. However, this argument is belied by the plain allegations of the AMCC.

As the AMCC explains, Defendants unilaterally reported AWPs to the Publishers and had exclusive control over their accuracy. ¶¶ 3, 136-38, 161-62. Defendants directed medical providers to take advantage of the AWP spreads so that the providers would prescribe the drugs with the most inflated AWPs to Plaintiffs and the Class. ¶¶ 4, 163-64. Defendants provided similar incentives to PBMs to take advantage of the lucrative AWP spreads so that Defendants would have the benefit of having their drugs placed on the PBM formularies. ¶¶ 5, 172-73. Moreover, Defendants actively concealed, and caused others to conceal, information that the AWPs were deliberately overstated. ¶¶ 7, 191-97. As a result of Defendants' scheme, Plaintiffs suffered harm by substantially overpaying for drugs based on artificially inflated AWPs. This harm certainly was a foreseeable, and indeed, an intended consequence of Defendants' deceptive conduct, as Defendant GSK itself envisioned. *See* ¶ 395. Certainly, the so-called "intervening actors" who were provided incentives to act as Defendants instructed, merely advanced – and did not break – the chain of causation that began with Defendants. *See supra* Section V.D.[27] Accepting these averments and all reasonable inferences as true, Plaintiffs have unequivocally pled that Defendants were a direct and proximate cause of Plaintiffs' injuries.

Nor does the lone case cited by Defendants, *Oliveira v. Amoco Oil Co.*, 776 N.E.2d 151 (Ill. App. Ct. 2002), suggest otherwise. In *Oliveira*, the court only addressed the proximate causation pleading requirements where the theory of liability was based on a false advertisement claim. *Oliveira*, 776 N.E.2d at 164. Here, however, Plaintiffs do not plead false advertising. Moreover, unlike the plaintiffs in *Oliveira*, Plaintiffs here have expressly alleged that they were ***deceived*** by Defendants' scheme.

Defendants further argue that the AMCC does not allege causation because it fails to allege that the actual publication of the AWPs ***caused*** Plaintiffs to purchase more drugs. Defs. Mem. at 30-31. This argument misses the point. Again, this is not a false advertisement case.

[27] Rather than repeat arguments already made in great detail above and unnecessarily prolong this memorandum, Plaintiffs refer the Court back to Section V.D.'s description of causation in the context of RICO.

Plaintiffs need only aver that there is a causal connection between Defendants' deceptive practices and Plaintiffs' injuries. Here, they have alleged that Defendants' scheme caused them to make overpayments for medications. Accordingly, Defendants' arguments are meritless.

B. Plaintiffs Have Properly Identified Defendants' Deceptive Practices

Defendants contend that their disputed conduct does not constitute "deceptive" or "misleading" practices under the relevant consumer statutes. Defs. Mem. at 31-33. Well-established law and the allegations of the AMCC belie this argument.

To demonstrate deception under each of the consumer protection statutes at issue, Plaintiffs need only show that the practice has a tendency or capacity to deceive consumers.[28] Here, the AMCC alleges numerous material facts underlying Defendants' deception. For example, Plaintiffs aver that Defendants failed to disclose that the published AWPs do not reflect the true average wholesale price of the drugs they sell. *See* ¶¶ 3,7 191-97, 687. The AMCC further alleges that Defendants did not tell consumers that they intentionally inflated the AWPs to increase their respective market share and profitability at the expense of consumers. *Id.* Nor did Defendants reveal that they encouraged Medicare Part B providers to prescribe medications based on the "spread" rather than for medical reasons and thereby increased the co-payments made by Medicare Part B participants. *Id.*

Defendants argue that such conduct is not deceptive because they reported their AWPs to private publications and ***not*** directly to Plaintiffs and therefore the AWPs could not have "lured" consumers to purchase the overpriced medications. Defs. Mem. at 32. This is a red herring. Of course, Plaintiffs did not decide to purchase drugs based on prices listed in the *Red Book*. However, that does not render Defendants' misconduct any less deceptive. Defendant's caused

[28] *Freeman v. Time, Inc.*, 68 F.3d 285, 288 (9th Cir. 1995) (California Law); *State v. Gardiner*, 2000 WL 973304, *4 (Del. Super. Ct., June 5, 2000) (Delaware Law); *Davis v. Powertel, Inc.*, 776 So. 2d 971, 974 (Fla. Dist. Ct. App. 2000) (Florida Law); *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 938 (7th Cir. 2001) (Illinois Law); *Shaw Indus. v. Brett*, 884 F. Supp. 1054, 1056 (M.D. La. 1994) (Louisiana Law); *Sutton v. Viking Oldsmobile Nissan, Inc.*, 611 N.W.2d 60, 64 (Minn. Ct. App. 2000) (Minnesota Law); *In re Shack*, 426 A.2d 1031, 1034 (N.J. App. Ct. 1981) (New Jersey Law); *Marcus v. AT&T Corp.*, 138 F.3d 46, 64 (2d Cir. 1998) (New York Law); 73 Pa. Stat. § 201-1 *et seq.* (Pennsylvania Law); Tex. Bus. & Com. Code §§ 17.41 B 17.63 (Texas Law); *Robinson v. Avis Rent A Car Sys.*, 22 P.3d 818 (Wash. Ct. App. 2001) (Washington Law).

the inflated AWPs to be published with the specific goal of giving the people and entities who control market share (PBMs and medical providers) an incentive to overcharge Plaintiffs and the Class. Moreover, Plaintiffs had no way of knowing that the AWPs were vastly inflated and that they were substantially overpaying for drugs. The fact that Defendants went to great lengths to conceal these facts from the public is further evidence that they knew that consumers would be outraged to learn of their deceptive conduct.

Defendants cite *Daaleman v. Elizabethtown Gas Co.*, 390 A.2d 566, 569 (N.J. 1978), for the proposition that state laws do not apply where alleged misrepresentations were not made to plaintiffs. Defs. Mem. at 32. However, *Daaleman* does not stand for this proposition. In *Daaleman*, the plaintiffs alleged that the defendant, a privately held public utility company operating under the jurisdiction of the state PUC, overcharged customers by improperly including certain automatic price adjustments to account for a rise in the cost of purchasing and storing natural gas. The *Daaleman* court merely held that this particular billing practice did not constitute a "selling or advertising" practice within the meaning of the New Jersey Consumer Fraud Act, N.J. Stat. Ann §§ 56:8-1 – 56:8-24 ("NJCFA"), and that the state public utility commission had exclusive jurisdiction over this specialized issue. Nothing in the opinion suggests that the NJCFA would not apply to a defendant that reported false prices to a publisher with the intended purpose of deceiving consumers.

Defendants also argue that Plaintiffs could not have been deceived by Defendants' conduct because Plaintiffs negotiated with PBMs to pay for drugs at discounts off AWP and therefore knew that published AWPs "reflect undiscounted prices." Defs. Mem. at 32. This argument defies logic and is factually inaccurate. One cannot logically deduce from the fact that some Plaintiffs were able to negotiate a discount off AWP, that the AWP must be an undiscounted sticker price. To the contrary, a more reasonable conclusion would be that any discount off AWP was the product of negotiation and good fortune because AWP is an "average," and therefore, by definition, some purchasers paid prices above AWP while others

paid prices below AWP. Plaintiffs certainly could not have known the vast degree to which Defendants overstated AWPs.

Plaintiffs also can establish liability under the relevant consumer protection statutes for the additional reason that the statutes prohibit any "unconscionable" business practices. The AMCC alleges that Defendants engaged in unconscionable business practices. *See, e.g.*, ¶¶ 686-87. Thus, for purposes of determining whether Defendants violated the consumer protection statutes by unconscionable business practices, the only issue is whether the manufacturers actually engaged in such a scheme or practice. Here, Plaintiffs allege that Defendants took unfair advantage of unsuspecting consumers who were unable to protect their interests by causing them to overpay for medications. Thus, Plaintiffs have adequately pled deceptive and unconscionable acts.

C. Plaintiffs Have Standing to Sue Under the Consumer Statutes

Defendants' assert a number of reasons why Plaintiffs lack standing under the consumer statutes of Delaware, Florida, Louisiana, New Jersey, Pennsylvania, and Washington. Defs. Mem. at 33-34. However, each of their objections is meritless.

Defendants first argue that the Delaware Deceptive Trade Practices Act precludes private causes of action. Defs. Mem. at 33. However, Plaintiffs assert their claim under the Delaware Consumer Fraud Act, which provides for private causes of action. *See Young v. Joyce*, 351 A.2d 857 (Del. 1975) (holding that private causes of action are available under 6 Del. Code § 2525).

Defendants next contend that only Florida residents can bring a cause of action under the Florida Trade and Unfair Practices Act ("FTUPA"). Defs. Mem. at 33. However, a Florida appellate court, after conducting a lengthy analysis on the issue, held that non-residents ***can*** maintain an action under the FTUPA. *Millennium Communs. & Fulfillment, Inc. v. Florida*, 761 So. 2d 1256 (Fla. Ct. App. 2000) (holding that FTUPA applies to commercial transactions between Florida corporations and non-residents). Notably, the one case that Defendants cite,

OCE Printing Sys. USA, Inc. v. Mailers Data Servs., Inc., 760 So. 2d 1037 (Fla. Ct. App. 2000), lacks precedential value because it is bereft of any legal analysis on the issue.

Defendants further argue that Plaintiffs lack standing because some Louisiana courts have held that only direct consumers and business competitors have standing under Louisiana's Unfair Trade Practices Act ("LUTPA"). But Defendants ignore the fact that a number of Louisiana courts have held to the contrary, finding that a plaintiff need not be a consumer or a competitor to maintain a private cause of action under LUTPA. *See Capitol House Preservation Co. v. Perryman Consultants, Inc.*, 725 So. 2d 523, 530 (La. Ct. App. 1998) ("Although business consumers and competitors are included in the group afforded this private right of action, Louisiana courts have repeatedly held they are not its exclusive members."); *Jarrell v. Carter*, 577 So. 2d 120, 123 (La. Ct. App. 1991) (holding that the consumer fraud statute "confers a right of private action on '[a]ny person who suffers any ascertainable loss of money or movable property").

Defendants next argue that Plaintiffs are not consumers under the New Jersey Consumer Fraud Act ("NJCFA") "because they do not 'diminish or destroy the utility' of the prescription drugs" named in the AMCC. Defs. Mem. at 34. Defendants are mistaken. In fact, the Second Circuit recently found otherwise under similar facts. In *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir. 2003), plaintiff health insurers brought claims against a drug manufacturer seeking recovery of the purchase price of a diabetes drug purchased for its insureds that was fraudulently promoted as being safer and more effective than alternatives. In finding in the plaintiffs' favor, the court explained:

> Although this court has not to date held that insurance companies are, in all instances, the "purchasers" of the drugs for which they reimburse pharmacies, we, like several other courts, have indicated that in a variety of contexts they are the buyers. (Citations omitted.) Moreover, and more directly relevant to this case, perhaps, Plaintiffs point out that this and other courts have long recognized the right of [health benefit plans] to recover from drug companies amounts that were overpaid due to illegal or deceptive marketing practices. *See, e.g., Hartford Hosp. v. Chas. Pfizer &*

> *Co.*, 52 F.R.D. 131, 133 (S.D.N.Y. 1971) (approving $10 million class action settlement of antitrust claims brought by insurance plans against drug companies). [*Id.* at 349-50.]

Here, as in *Desiano*, Plaintiffs have paid the costs (or a large portion thereof) for the end-users. Thus, there is no reason why the health benefit plan Plaintiffs in this case – organizations that have suffered substantial ascertainable losses as a result of Defendants' deceptive conduct – should be denied their right to be made whole like any consumer. Furthermore, the case that Defendants rely upon, *City Check Cashing, Inc. v. National State Bank*, 582 A.2d 809 (N.J. Ct. App. 1990), is easily distinguishable. In *City Check Cashing*, the court compared the plaintiff to a typical wholesaler of goods and ruled that a wholesaler could not bring a claim against the manufacturer. Here, however, Plaintiffs are not in the position of wholesalers of goods, but rather are the actual payers of the costs (or a large portion thereof) of the end-users. Accordingly, *City Check Cashing, Inc.* does not apply.

Defendants' fifth argument is that the AMCC is defective under Pennsylvania law because it fails to allege that Plaintiffs purchased the drugs "primarily for personal, family or household purposes." Defs. Mem. at 34. Under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("PUTPCPL"), "any person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss . . . may bring a private action. . ." 73 Pa. Stat. § 201-9.2. However, the allegations in the AMCC satisfy these requirements. The obvious purpose of purchasing drugs is to use the medications for personal purposes. *See Valley Forge Towers S. Condominium v. Ron-Ike Foam Insulators, Inc.*, 574 A.2d 641 (Pa. Super. Ct. 1990) (finding that a condominium association's purchase of a replacement roof involved a purchase for personal, family or household purposes). Thus, the drugs were purchased for personal use. At worst, the use is part consumer and part

commercial and therefore should be deemed a consumer one. *See Marascio v. Campanella*, 689 A.2d 852 (N.J. Ct. App. 1997). Accordingly, Plaintiffs have standing under Pennsylvania law.[29]

Defendants' reliance on *Waldo v. North Am. Van Lines, Inc.*, 669 F. Supp. 722, 725-26 (W.D. Pa. 1987), is misplaced. In *Waldo*, the court held that the state consumer fraud act did not apply because the purchased item was for ***business*** purposes and therefore did not have a "consumer nature." In contrast, here, Plaintiffs never even took actual title to the medications at issue in this case. Nor did they sell them as part of a wholesale or distribution business. Instead, they simply reimbursed on behalf of the end user. Therefore, all of the payments were consumer oriented in nature.[30]

Defendants lastly argue that Plaintiffs lack standing under Washington law "because they have not purchased drugs directly from the defendants." Defs. Mem. at 34. To support their argument, Defendants mistakenly rely on *Blewett v. Abbott Labs*, 938 P.2d 842 (Wash. Ct. App. 1997). However, in *Blewett,* the plaintiffs, who were indirect purchasers, alleged that defendant engaged in ***price-fixing*** and brought a consumer protection claim under: (i) an anti-price-fixing provision (RCW 19.86.030), and (ii) a misleading and deceptive conduct provision (RCW 19.86.020). The *Blewett* court concluded that no recovery was available for indirect purchasers under the price-fixing provision and consequently would not allow plaintiffs to recover on the same price-fixing allegations under RCW 19.86.020. However, the present case is distinguishable from *Blewett* because Plaintiffs have alleged independent misleading and deceptive

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[29] Defendants similarly argue that the alleged misconduct at issue is not "consumer oriented" under New York law. Defs. Mem. at 35. However, because the AWP scheme causes universal price distortion in connection with the purchase and reimbursement of all relevant pharmaceuticals, it is a matter that greatly affects the public interest of New York. *See Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995) (stating that the critical issue for determining whether certain conduct is "consumer oriented" under New York law is whether "the matter affects the public interest in New York, not whether the suit is brought by a consumer or a competitor"); *New York v. Feldman*, 210 F. Supp. 2d 294, 301 (S.D.N.Y. 2002) ("A defendant engages in 'consumer-oriented' activity if his actions cause any 'consumer injury or harm to the public interest.'").

[30] Under the PUTPCPL, an organization or entity can make purchases for a consumer purpose. *See S. Kane & Son Profit Sharing Trust v. Marine Midland Bank,* No. 95-CV-7058, 1996 WL 200603 (E.D. Pa. Mar. 8, 1996) (holding that a trust's purchase of securities was primarily for the personal purposes of those beneficiaries because it was formed to act on behalf of individual employee members of a benefit plan).

conduct (other than price-fixing) that forms the basis of their claim under RCW 19.86.020, it is not a price-fixing case.

Accordingly, all of Defendants' challenges to standing are meritless.

D. Plaintiffs Are Not Required to Plead Reliance

Defendants contend that Plaintiffs must prove reliance to state a valid claim under the consumer protection statutes of Pennsylvania and New York. Defs. Mem. at 35. Defendants, however, misconstrue Plaintiffs' claims and ignore the body of law interpreting these statutes.

Neither section 201-2(v)(xxi), the so-called "Catchall" provision of the PUTPCPL[31], nor sections 349 and 350 of New York's General Business Law require Plaintiffs to plead actual reliance to allege a claim for ***deceptive practices***. *See Commonwealth v. Percudani*, 2003 WL 21211325 (Pa. Cmmw. May 27, 2003) (Pennsylvania law); *Weiler v. Smithkline Beecham Corp.*, 2001 WL 1807382 at *2 (C.P. Phila. Oct. 8, 2001) (Pennsylvania law) (holding that reliance is not required under the statute's Catchall Provision where, rather than a common law fraud case, the action is based on deceptive practices); *Blue Cross & Blue Shield of N.J., Inc. v. Phillip Morris, Inc.*, 178 F. Supp. 2d 198, 231 (E.D.N.Y 2001) (New York law) (finding that the act eliminates the traditional requirements of reliance and scienter).

This "Catchall Provision" of the UTPCPL permits a plaintiff to establish a valid claim by proving ***either*** "the elements of common law fraud, ***or*** that Defendant's deceptive conduct caused harm to the Plaintiff." *Zwiercan*, 2002 WL 31053838 at *2 (emphasis added).

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[31] Significantly, in 1996, the Pennsylvania legislature amended the Catchall provision to prohibit deceptive conduct in addition to fraudulent conduct as follows:

> (xxi) Engaging in any other fraudulent ***or deceptive*** conduct which creates a likelihood of confusion or misunderstanding.

UTPCPL § 201-2(v)(xxi) (emphasis added to show added language). Prior to the amendment, the Catchall provision proscribed only "fraudulent conduct" creating a likelihood of confusion or misunderstanding. Although some Pennsylvania Superior courts have interpreted the provision as still requiring plaintiffs to plead the elements of common law fraud, the Pennsylvania Commonwealth Court recently discredited that line of cases for failing to discuss the 1996 amendments to the Law and held that the only reasonable construction of the Catchall provision under settled rules of statutory interpretation requires that the added term "or deceptive" be ascribed meaning. *Percudani*, 2003 WL 21211325 at *3.

Nor do the cases cited by Defendants suggest otherwise. For example, *Weinberg v. Sun Co., Inc*, 777 A.2d 442 (Pa. 2001), merely held that a plaintiff must demonstrate actual reliance on a false advertisement in a false advertising case.[32] Similarly, *McGill v. General Motors Corp.*, 231 A.D.2d 449 (N.Y. App. Div. 1996), is unavailing because it too held that false advertisement claims should be dismissed absent a showing that "***any*** plaintiff relied upon ***or even knew about***" the allegedly false advertisements at issue. *Id.* at 450 (emphasis added).[33] However, Plaintiffs do not assert false advertising claims here and are consequently are not required to plead reliance.

VIII. THE AMCC PROPERLY INCLUDES MULTIPLE-SOURCE DRUGS IN THE AWP INFLATION SCHEME

In three scant pages of argument, Defendants seek to have this Court dismiss the vast majority of drugs from this case simply because they are multiple-source drugs. In doing so, Defendants plainly ignore the allegations of the AMCC, cast aside major criminal and civil investigations of their conduct relating to multiple-source drugs over many years, pretend they are unaware that some of the most egregious AWP price manipulation occurs in the generic/multi-source arena, and claim the existence of regulatory practices that nowhere appear in the record (let alone this 12(b)(6) context). The arguments wholly lack merit.

A. The AMCC's Detailed Allegations Regarding Multi-Source Drugs

The AMCC is replete with examples of AWP price fraud for multi-source drugs.[34] As the AMCC alleges, Defendants "AWP fraud is most exacerbated for generic drugs or for brand name

[32] *Debbs v. Chrysler Corp.*, 2002 WL 3138888 (Pa. Super. 2002), is not applicable here because *Debbs* involved a claim that originated in 1990, before the 1996 amendment broadening the Catchall Provision of the UTPCPL.

[33] Moreover, because New York courts construe the state's consumer fraud provisions liberally, *see Teller v. Bill Hayes, Ltd.*, 213 A.D.2d 141, 146; *Blue Cross,* 178 F. Supp. 2d at 231, plaintiffs were not required to plead the elements of fraud with particularity in order to state a claim under § 350.

[34] Brand name drugs are typically those drugs that still enjoy patent protection, but can include drugs that continue to be sold under a brand name even though generic competition (in a form of biological or therapeutic equivalents of the brand name) has entered that market. Generic drugs are drugs that are the FDA-approved bio-equivalent of a brand name drug. The phrase "multi-source drugs" is a broader expression for generics under a circumstance where brand name drugs continue to be marketed even through generic competition has entered; in those circumstances, there are multiple sources from which the same FDA-approved bio-equivalent pharmaceutical may be purchased.

drugs for which there are biological but therapeutic equivalents." ¶ 179. The rational for this, as explained in the AMCC, is simple: under circumstances where biological or therapeutic equivalents are acknowledged to exist, competition is most fierce and, accordingly, the temptation or actuality of AWP inflation to create profit incentives to increase or maintain market share is highest. As the AMCC chronicles, competition among biological or therapeutic equivalents, along with the incentive it creates for practicing over-reimbursement, settings in which drugs are reimbursed or purchased, whether in the public or private arena, and whether in Medicare or Medicaid. In "the private payor arena, generic drug reimbursement is closely tied to the published AWP for a generic drug." ¶¶ 184-85. As a result, generic "drug makers are able to push market share for their generic products by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain." ¶ 183. The AMCC also describes how PBMs utilize generic drug pricing to their advantage, through shifting MAC price listings to their advantage and to the disadvantage of plan sponsors. ¶ 182.

Similarly, generic or multi-source over-reimbursement abuse occurs in the public payor arena. As Defendants are well aware, Medicaid reimburses generic drugs on the basis of a specific generic drug maker's generic product; as a result, classic AWP price inflation runs for the benefit of generic makers and to the disadvantage of the federal government. Furthermore, the AMCC alleges that within the Medicare Part B arena multi-source products are also able to gain or lose market share depending upon how aggressively they engage in over-reimbursement. ¶¶ 184, 189.

Because competition is most acute in the multi-source context, it should come as no surprise that the vast majority of examples of AWP abuse occur in the multi-source arena. Among many examples, the AMCC sets forth the following at paragraph 187[35]:

[35] *See* ¶¶ 208, 214, 280, 283-84, 293, 312, 323, 325, 336, 343, 353, 359, 360, 37, 373-74, 466, 472, 486-87, 503, 534 and 535, for other examples of multi-source AWP abuse.

Defendant	Multisource Drug	*RedBook* AWP	DOJ Determined Actual AWP	Percentage Spread
Abbott	Sodium Chloride	$670.89	$3.22	20,735%
Baxter	Dextrose	$928.51	$2.25	41,167%
Baxter	Sodium Chloride	$928.51	$1.71	54,199%
Boehringer Group	Leucovorin Calcium	$184.40	$2.76	6,581%
B. Braun	Sodium Chloride	$11.33	$1.49	660%
BMS Group	Etoposide (Vepesid)	$136.49	$34.30	298%
Dey	Albuterol Sulfate	$30.25	$9.17	230%
Immunex	Leucovorin Calcium	$137.94	$14.58	846%
Pharmacia	Etoposide	$157.65	$9.47	1,565%
Sicor Group	Tobramycin Sulfate	$342.19	$6.98	4,802%
Watson	Vancomycin HCL	$70.00	$3.84	1,567%

In sum, the AMCC sets forth scores of examples of multi-source drugs for which fraudulent AWPs have resulted in overpayments over the years. These allegations – not Defendants' denials – should control in this 12(b)(6) context.

B. Defendants "We Have No Incentive" Argument Makes No Sense

Ignoring the controlling allegations of the complaint, defendants argue (or more accurately, assert as a matter of fact outside the record), that the regulatory practice of CMS is to cause uniform billing of multi-source pharmaceuticals strictly on the basis of "the lesser of the median average wholesale price for all sources of a generic form" or the lowest AWP for the brand name. Defs. Mem. at 36. From this factual assumption, Defendants argue that there can be no incentive for any manufacturer of a multi-source drug to increase its AWP. The logic, and the factual assumptions, are simply wrong.

First, Defendants' argument that Medicare Part B is the regime that controls all multi-source drug pricing is wrong. Medicare Part B covers only a narrow band of injectible drugs; as a result, the Medicare Part B pricing regime has no effect whatsoever on drugs not eligible for Medicare Part B coverage.

Second, even for the narrow band of multi-source drugs covered by Medicare Part B, those drugs are not ***exclusively*** reimbursed by Medicare Part B; indeed, for most multi-source drugs, the lion's share of reimbursements occur outside the context of Medicare Part B. Accordingly, the Medicare Part B pricing regime for multi-source drugs does not control the manner, or the incentives, for AWP price inflation.[36]

Third, even within the Medicare Part B regime, the Defendants (as the AMCC alleges) have repeatedly been documented to have directly caused over-reimbursement for multi-source drugs, despite the regulatory requirement (but perhaps not the regulatory practice) of using the median AWP of multi-source drugs. Since Defendants go outside the complaint[37] to posit this argument, Plaintiffs refer to the following reports which are to the contrary:

- As one industry observer has written, "The AWP, while not the cost paid by retailers, still provides the basis for much retail pricing, with retailers euphemistically referring to the difference between their actual cost and the AWP as 'earned discount.'" ... ***This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs.*** ... Soon, many other generic companies instituted similar policies. ... It is also common for the AWP of a generic product to remain stable while the actual selling price declines." PP. 36-37). (E. M. Kolassa, *Elements of Pharmaceutical Pricing*, The Pharmaceutical Products Press (1997)). (Cited in AMCC ¶ 185.) *See also* J. Sokolovsky, *"Payment system for prescription drugs covered under Part B – Presentation to Senate Committee on Finance staff."* Medicare Payment Advisory Commission. (Feb. 28, 2003), at p. 10 ("Difference between AWP and acquisition costs are highest for products available from more than one source."). (Attached as Exhibit B to Affidavit of Tom Sobol ("Sobol Aff.").

- In a 2001 investigation, GAO found that: "Two drugs, albuterol sulfate and ipratropium bromide, used with DME for respiratory conditions, account for most of the pharmacy-supplied drugs paid for by Medicare. In 2001, they were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP. Other high-volume DME-administered drugs had prices averaging 69 percent and 72 percent less than AWP. These findings are consistent with prior studies of similar drugs [albuterol]." (*Medicare Part B Drug Program Payments Should Reflect Market Prices.* GAO-01-1142T. (Sep. 21, 2001). Sobol Aff. Ex. C.

[36] Although many Medicare Part B eligible multi-source drugs are alleged in the AMCC to have suffered unlawful over-reimbursement as a result of incentives that exist outside of the Medicare Part B context, this does not mean that those private persons are paying co-payments for Medicare but the charges are not affected by those unlawful and fraudulent AWPs. The incentives that result in multi-source drug makers to inflate AWPs have the spillover effect of equally impacting the reimbursement rates set in Medicare Part B.

[37] The studies cited below were all used in drafting the AMCC.

- In 2002, the GAO found that "discounts . . . were largest for products that could be obtained from more than one source." (P. 7). (*Medicare Outpatient Drugs – Program Payments Should Better Reflect Market Prices.* GAO-02-531T. (Mar. 14, 2002). Sobol Aff. Ex. D.

- In a 2002 audit, HHS determined that "actual generic drug acquisition was a national average of 65.93 percent below AWP. Our previous estimate, based on Calendar Year (CY) 1994 pricing data, showed a discount of 42.45 percent below AWP for generic drugs. As a result, this review showed an increase of 55.31 percent in the average discount below AWP for generic drugs from 1994 to 1999." (P. 3, Executive Summary). (*Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products.* A-06-01-00053. (Mar. 4, 2002). Sobol Aff. Ex. E.

- "[U]nder this system, the GAO found that the differences between AWP and the widely available catalog prices actually were largest for the products where there were more generics available.... [cost of the product] remains the same. AWP goes up, and if you do the subtraction the resulting profit or the provider margin for that drugs goes up without the cost to the manufacturer going down." (PP. 3-4). (Minutes. Medicare Payment Advisory Commission Public Hearing. (Sept. 13, 2002). Sobol Aff. Ex. F.

- In a recent report to Congress, the Medicare Payment Advisory Commission, an independent federal body established by the BBA of 197, reported on variations in Medicare purchasing. One of the issues examined was "the system creates incentives for manufacturers to raise prices". (P. 150). "Incentives for increasing AWPs – ***In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. For these drugs, manufacturers compete to increase their market share.*** This competition can take two forms. A manufacturer may raise the AWP for its product without changing the price charged to purchasers. ... [or] leave the AWPs at existing levels, and offer larger discounts directly to physicians who choose their drugs over products offered by competitors." (P. 156). (*"Report to Congress: Variation and Innovation in Medicare."* Medicare Payment Advisory Commission. (Jun. 12, 2003)). Sobol Aff. Ex. G.

Fourth, Defendants ***assume*** that the regulatory provision for charging the "median" of the AWPs for multi-source drugs is operative and consistent and incapable of manipulation or exploitation. But this assumption is a disputed fact. For example, GAO recently chronicled that carriers (not CMS itself) established drug reimbursement amounts throughout the country and that those carriers issued markedly different reimbursement amounts for multi-source drugs. In a 2001 report that compared acquisition cost with reimbursement allowances, the GAO found that: "Widely available prices in 2001 reflected average discounts of 78 percent from the AWP for ipratropium bromide and 85 percent for albuterol, two DME-delivered inhalation therapy drugs.

That accounts for most of Medicare payments to pharmacy suppliers."[38] (P. 4). Both drugs are multi-source drugs. *Id.* at 18. Further, GAO reported: "Within these guidelines, each carrier contracting with Medicare to process claims has discretion to determine which NDCs should be used to calculate the payment rate for each HCPCS code. This can lead to variation in payment amounts among carriers for the same HCPCS-coded drug." *Id.* at 10 n.16.

Similarly, when Medicare Part B reimbursed multi-source drugs on the basis of generic prices (and ignoring brand name prices), generic makers exploited this loophole by grossly exaggerating the spread for their generic prices even to points where the generic prices far exceeded the brand name price. In a report on the impact of high-priced generic drugs on the Medicare and Medicaid programs, HHS concluded that ***"high-priced generic drugs have a significant financial impact on Medicare and Medicaid reimbursement."***[39] *Id.* at ii. (Emphasis added). HHS also found that in some instances, the AWP for generic products was three to four times greater than the brand price. *Id.* at i. Moreover, HHS found that "Prior to January 1, 1998... [f]or drugs with generic versions, the carriers determined reimbursement based on the median of all AWPs for the generic drugs." *Id.* at C-2. Of the four drug codes reviewed (vancomycin, etoposide, kanamycin sulfate and digoxin), all four had at least two generic versions available in 1997. In addition, all had between one and four generic versions with published prices higher than brand prices.

The plain fact is that the spread still exists and each generic manufacturer leap frogs each other increasing the spread and, therefore, causing generics to have the largest spreads. This fact of ongoing reimbursement spread abuse in the multi-source area was reiterated as recently as three weeks ago, when CMS observed:

> In general the 'spread,' in percentage terms, is larger for the generic drugs examined in the studies than for brand drugs. This is consistent with our understanding that when actual market prices

[38] *Payments for Covered Outpatient Drugs Exceed Providers' Cost.* GAO-01-01118. (Sep. 21, 2001). Attached as Ex. H to Sobol Aff.

[39] *The Impact of High Priced Generic Drugs on Medicare and Medicaid, Draft Report.* Sobol Aff. Ex. I.

> decline with the introduction of generic competition, the list AWPs do not usually experience a corresponding decline of the same magnitude.

Federal Register, Volume 68, No. 161 at 50,428 (August 20, 2003).

Finally, if one-steps back from the situation and observes Defendants' arguments in the stark light of their own pricing behavior, Defendants' arguments simply make no sense. If Defendants have nothing to gain by grossly overstating the AWP for multi-source drugs, then why is it that they have done so, and done so to such an egregious extent? If truthful AWP reimbursement publication really exists in the multi-source arena (because as defendants would have it there is no motivation for such conduct), then how is it that public and private authorities have chronicled scores of AWP fraudulent abuse in the multi-source drug arena? Why have several drug makers paid multi-million dollar civil settlements relating to multi-source drugs? Why have many drug makers narrowly escaped criminal indictments through the payment of significant fines and making agreements that constrain future corporate behavior? These questions – rhetorical as they are – highlight the untenability of Defendants' so-called "logical" arguments with respect to multi-source drugs and undercut their validity. The AMCC pleads a viable AWP inflation fraud within the context of multiple-source drugs, and Defendants' arguments on this issue should be flatly rejected.

IX. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copies of the foregoing Plaintiffs' Memorandum of Law in Opposition to Defendants' Consolidated Motion to Dismiss the Amended Master Consolidated Class Action Complaint (Redacted) to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2., this 15th day of September, 2003.

By: _____

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